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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,892

06/18/2007

Markus Muller

075422-0020

2347

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

07/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,892	<b>Applicant(s)</b> MULLER ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 17-20 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Upon considering Applicants' response to the office action and the amendment, the finality of that action is withdrawn and the prosecution is reopened.

***Status of the application and response to the arguments***

2. Claims 1-14, 17-20 are pending. Claim 15-16, 21-22 are cancelled. The Applicants' arguments and the amendment were fully considered and found persuasive in-part for the reasons that follow. The rejections that are not reiterated herein are withdrawn. The claim 1 is amended to incorporate the limitations of claim 16 (now cancelled). Applicants' arguments with regard to denatured nucleic acid and use of RNase in the prior art cited by the examiner, were fully considered and found unpersuasive because the instant claims are in open 'comprising' format and as stated in MPEP 2111.03 any unrecited elements or steps are within the scope of the claims. In addition, the limitations (no need of denaturing and RNase Treatment) upon which the arguments depend are not present in the claims, as stated in MPEP 2145, Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The prior art Colpan et al. is applicable to the newly amended claims as discussed below. This action is made Non-Final.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aberin et al. (US 6,406,892) in view of Colpan (US 5,990, 301).

Aberin et al. teach a method of claims 1, 17, for the chromatographic separation of a nucleic acid mixture wherein plasmid DNA is separated from other components of the mixture, wherein the method comprises

(a) the nucleic acid mixture is adjusted with one or more alkali salts and/ or alkaline earth salts in aqueous solution to a conductance that is equivalent to a conductance of 70 mS to 95 mS at a pH of 4.8 to 5.4 at temperature of 20<sup>0</sup> C (see col. 2, line 47-67, col. 3, line 1-13);

(b) the nucleic acid mixture is brought into contact with a chromatographic stationary phase (see col. 3, line 14- 44);

(c and d) the stationary phase is then washed at least once with a solution comprising an alkaline earth salt in a concentration ranging from 100mM to 240mM based on pH of 7 to 7.4 and the plasmid DNA bound to the chromatographic stationary phase is subsequently eluted with

a solution comprising an alkali earth salt in a concentration of 270mM or higher based on pH 7 to 7.4 (see col. 3, line 6-54, col. 6, line 9-15).

With regard to claims 2-13, 18, Aberin et al. teach that the alkali salts comprise alkali halides and the solution for conductance, wash and elution solutions comprise KCl or NaCl at concentration ranging from 1.0 to 10 M based on pH 5 to 8.0 (see col. 3, line 6-54, col. 6, line 9-15).

With regard to claims 14, Aberin et al. teach that said chromatographic stationary phase is an anion exchanger that comprises hydroxyapatite (see col. 3, line 20-44).

With regard to claim 20, Aberin et al. teach nucleic acid mixture is a cleared lysate from prokaryotic cells and the method purifies plasmid DNA and the plasmid DNA is used for gene therapy or genetic vaccination (see col. 3, line 45-65, col. 1, line 11-54).

Although Aberin et al. teach the use of a stationary phase, Aberin et al. did not specifically teach preparing silanized stationary phase.

Colpan et al. teach a method for purifying plasmid DNA wherein the method comprises preparation of the silanized stationary phase, which enabled packed diatomaceous useful in removal of endotoxins (see col. 7, line 9-67, col. 4, line 60-67, col. 5, line 1-67).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the method as taught by Aberin et al. with the step of preparation of stationary phase as prepared by Colpan et al. to achieve expected advantage of developing an improved and sensitive nucleic acid isolation method because one skilled in the art would have a reasonable expectation of success that the combination of method of Aberin et al. and the method of preparing stationary phase as taught by Colpan et al. would

result in efficient separation of plasmid DNA with depleted endotoxin (see col. 7, line 9-67, col. 4, line 60-67, col. 5, line 1-67) and such a modification is considered obvious over the cited prior art.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637